

K121219

SEP 25 2012

510(k) Summary

Date Prepared: April 20, 2012

Applicant: Medtronic Ireland
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Proprietary Name: Medtronic Attain Clarity™ Venogram Balloon Catheter

Model: 6225

Device Classification Name: Catheter, Percutaneous
Class II, 21 CFR 870.1250

Product Code: DQY

Device Description: The Attain Clarity™ 6225 Venogram Balloon Catheter contains one non-latex occlusion balloon catheter, one stopcock and one controlled stroke syringe. It is indicated for use within the coronary sinus and is intended for infusing contrast solutions into the coronary vasculature for occlusive venogram imaging. This device is available in one model, the Attain Clarity™ 6225 Venogram Balloon Catheter.

Indications For Use:	The Attain Clarity™ 6225 Venogram Balloon Catheter is indicated for use within the coronary sinus; it is intended for infusing contrast solutions into the coronary vasculature for occlusive venogram imaging.
Substantially Equivalent Devices:	<p>The Attain Clarity™ 6225 Venogram Balloon Catheter is similar to the following predicates with respect to intended use, design and technology:</p> <ul style="list-style-type: none"> • Attain™ 6215 Venogram Balloon Catheter (K012225, cleared August 28, 2001) • Oscor Occlusion Balloon Catheter, Model Venos™ (K081052, cleared June 18, 2008)
Summary of Technological Characteristics:	<p>The Attain Clarity™ 6225 Venogram Balloon Catheter is a non-latex occlusion balloon catheter designed for use within the coronary sinus for infusing contrast solution for occlusive venogram imaging.</p> <p>The balloon catheter consists of polymeric tubing with an infusion port and an inflation port in the main body of the catheter.</p> <p>The inflation port features a luer lock at the proximal end. Inflation is achieved through the use of a controlled stroke fixed volume syringe attached to a stopcock. The stopcock is manually attached to the balloon catheter. Both the stopcock and the syringe are supplied with the device.</p> <p>A silicone balloon is located near the distal end; a marker band is located proximally to the balloon to help with visualizing the location of the balloon under fluoroscopy. The infusion port has a luer lock at the proximal end.</p>
Summary of Studies:	<p>Device integrity testing was performed to support the equivalency of the Attain Clarity™ 6225 Venogram Balloon Catheter to the predicates.</p> <p>The following in-vitro bench tests were completed on the device:</p> <ul style="list-style-type: none"> • Dimensional testing • Balloon safety & performance testing • Catheter safety & performance testing • Compatibility testing • Packaging testing <p>The Attain Clarity™ 6225 Venogram Balloon Catheter met all specified design and performance requirements.</p>

Summary of Clinical Data: No clinical investigation has been performed for this device.

**Biocompatibility
Information:**

Biocompatibility testing for the Attain Clarity™ 6225 Venogram Balloon Catheter has been completed in accordance with the International Standard ISO10993-1:2009 "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing" for an external communicating devices with limited exposure i.e. whose contact with circulating blood is \leq 24 hours.

The following Biocompatibility tests were performed:

- Cytotoxicity Study using ISO MEM Elution method:
- ISO Maximisation Sensitisation Study
- ISO Acute Intracutaneous Reactivity
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogen Study in Rabbits
- ASTM In-vitro Hemolysis
- ASTM Partial Thromboplastin Time (PTT) Coagulation Testing
- C3a Complement Activation Assay Study
- SC5b-9 Complement Activation Assay Study
- In Vivo Thromboresistance Study in the Dog, Jugular Vein
- USP Physicochemical Tests for Plastic (Aqueous)

The biocompatibility evaluation completed verifies that the Attain Clarity™ 6225 Venogram Balloon Catheter is biocompatible.

Sterilization Validation:

The Attain Clarity™ 6225 Venogram Balloon Catheter will be sterilized using a validated Ethylene Oxide (EtO) to a minimum Sterility Assurance Level of 10^{-6} in compliance with ANSI/AAMI/ISO 11135-1.

Conclusion:

Through the data and information presented, Medtronic Ireland considers the Attain Clarity™ 6225 Venogram Balloon Catheter to be substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

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Wendy A. Saunders
Medtronic, Inc CRDM
8200 Coral Sea Street, MS MVS11
Mounds View, MN 55112

Re: K121219

Attain Clarity 6225 Venogram Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Saunders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

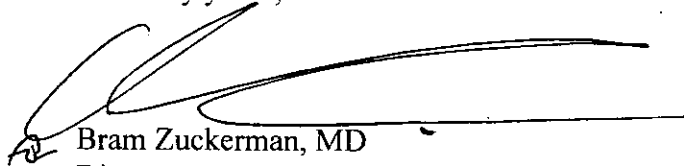
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram Zuckerman', with a long horizontal flourish extending to the right.

Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K121219

Device Name: Medtronic Attain Clarity™ 6225 Venogram Balloon Catheter

Indications for Use: The Attain Clarity™ 6225 Venogram Balloon Catheter is indicated for use within the coronary sinus; it is intended for infusing contrast solutions into the coronary vasculature for occlusive venogram imaging.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

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